



2020 Dow Center
June 30, 2014

Dr. Meredith Williams
California Department of Toxic Substances Control
Deputy Director
P.O. Box 806
Sacramento, California 95832-0806
Sent *via* email to SaferConsumerProducts@dtsc.ca.gov

Re: Comments and suggestions on the Safer Consumer Products Regulation initial draft Priority Products release and selection methods (June 30, 2014)

Dear Dr. Williams:

The Dow Chemical Company (Dow) appreciates the opportunity to provide comments on the California Department of Toxic Substances Control (DTSC or Department) initial draft Priority Products selection and release pursuant to the Safer Consumer Products (SCP) Regulation.

As a world leader in using science and technology to shape chemicals management improvements, Dow is well-positioned to use green chemistry to address the needs and challenges of a more demanding world. With over 700 employees and contractors at five manufacturing facilities in California, Dow has a vested interest in the SCP regulation and has been actively engaged in the statutory and regulatory process since its inception. Dow is a diversified company that delivers technology-based products and solutions to customers in approximately 180 countries through an industry-leading portfolio in high growth sectors such as packaging, electronics, water, coatings and agriculture.

While Dow maintains its commitment to the initial goal of the California Green Chemistry Initiative and appreciates DTSC's willingness to meet with stakeholders, we are concerned by the selection and release of the initial draft Priority Products. The identification process for the initial draft Priority Products did not benefit fully from industry stakeholder consultation, resulting in issues that we believe require further consideration and clarification by the Department before moving forward with the Priority Product Rulemaking Process and release of the 3-year Work Plan.

Therefore, we respectfully submit suggestions to improve the process and communication for future rounds of initial draft Priority Products.





We also adopt and support the comments made by the American Chemistry Council¹ (ACC) as well as additional comments submitted to the Department by Dow² specific to the selection and announcement of SPF as an initial draft priority product.

As described more comprehensively in the comments below, Dow urges DTSC to reconfigure the Priority Product identification process as follows:

- **Process improvements** (research and decision making/product identification/regulatory duplication): DTSC should improve the quality of research leading to draft Priority Product selections and announcements through industry stakeholder engagement as well as other means. DTSC should take full advantage of studies and regulatory reviews undertaken by private industry, academics, and other regulatory agencies, in order to bolster the Department's credibility and to ensure inclusion of accurate and consistent information. Dow also urges the Department to give careful consideration to the potential for regulatory duplication based on the activities of Federal programs and, where appropriate, explain why the product selections do not constitute regulatory duplication.
- **Communication strategy:** Communications by DTSC related to draft Priority Products should accurately reflect the Department's research and the intent of the Safer Consumer Products Regulation. Furthermore, communications should not inappropriately characterize priority products based on limited or draft assessments and should not prejudice their outcome within the program.

A. DTSC should improve the quality of research leading to draft Priority Product selection and announcement, engaging industry at the outset.

Dow is concerned with the lack of accurate information at time of initial draft Priority Product selection and subsequent release. We strongly urge the Department to improve the quality of research done in advance of product selection. Dow also notes specifically that the inclusion of Spray Polyurethane Foam (SPF) containing unreacted diisocyanates as an initial draft Priority Product did not reflect the implementation of a robust, objective research process. DTSC is basing the regulatory decision making process on incorrect understanding of the chemistry of SPF and its physical application. In order to achieve

¹ [Comments and suggestions on the Safer Consumer Products Regulation initial draft Priority Products release and selection methods, American Chemistry Council, June 30, 2014]

² [Comments on the Draft Initial List of Priority Products and Spray Polyurethane Foam Systems Containing Unreacted Diisocyanates, The Dow Chemical Company, June 30, 2014]



scientifically sound and supportable selections, Dow recommends the following improvements to the Priority Product research process and Profile development:

- DTSC should conduct thorough research on potential Priority Products and their chemistries and accurately identify the product-chemical combinations prior to announcing initial draft Priority Products and release of Product Profiles.
- DTSC should engage industry stakeholders directly, especially product manufacturers, to review and improve upon product-specific hazard and exposure and composition information prior to the release of the draft Priority Products. Industry consultation beforehand is critical to understanding the product value-chain, parties involved and “responsible entities,” chemistries, uses, exposures, breadth of toxicological data available, current voluntary and/or regulatory programs, and market impacts.
- DTSC has a few options available in order to gather data on potential Priority Products and Chemicals of Concern, and the Department should utilize options, such as data call-ins to obtain actual exposure data versus surrogates, for example. Data call-ins could also enable DTSC to better identify the potential responsible entities for the draft Priority Products.
- DTSC should recognize and appropriately leverage data and conclusions emanating from research conducted by State and Federal agencies, and as relevant, coordinate with other regulatory agencies. For instance, the United States Environmental Protection Agency has published significant literature³ on SPF, which does not appear to have been fully reviewed nor considered during research done at DTSC leading to the initial draft Priority Product selection and announcement.
- DTSC should provide definitions for and linkages between the phrases “potential public/aquatic exposure,” and “significant or widespread adverse impacts.” Currently these undefined phrases are causing confusion for manufacturers of the draft Priority Products. DTSC should be comprehensive and transparent in their assessment of potential product hazards and exposures as part of the assessment and inclusion of products in the program.

³ [http://www.epa.gov/dfe/pubs/projects/spf/spray_polyurethane_foam.html]

- Product profiles released to the public should be accurate, reasonable, and data-based. To minimize the potential for inaccuracies, DTSC should consider an internal or external peer-review process for Product Profiles before releasing them to the public, or, make clear that Product Profiles are in draft form and are subject to change. Additionally, DTSC should be cautious of discussing alternative chemicals and/or products in the Profile or other public documents in the absence of a thorough alternative analysis.
- Dow also urges the Department to consider in the rulemaking process the definition of “consumer” so as to avoid duplication with other entities such as CAL OSHA, having authority for worker safety in these areas. Further there is significant overlap and potentially conflict with other Federal activities, e.g., by US EPA in their Action Plan and Work Plan efforts to assess and regulate diisocyanates in SPF.
- DTSC should provide access to the material upon which the draft Priority Product selections were made. Currently the Priority Product Profiles contain incomplete citations or have broken reference links^{4,5}. References used in the Profiles should meet the definition of “reliable information” as defined in the SCP Regulation.

B. Communications by DTSC related to draft Priority Products should accurately reflect the Department’s research and the intent of the Safer Consumer Products Regulation.

Communications about the Safer Consumer Products regulatory activities and decisions have direct effects on the public, the regulated communities, and the success of the overall program. Realizing DTSC’s goals of advancing innovative materials and conducting alternatives analyses will require the cooperation of industry, government and other stakeholders. However, if DTSC pre-determines through its messaging the outcomes of Priority Product decisions, it will be difficult to meet the stated objectives.

- Language used by DTSC in the public documents (e.g., fact sheets, and Priority Product Profiles, DTSC presentations) associated with the three draft initial Priority Products should reflect the evolving nature of the Priority Product

⁴ [<http://www.irta.us/PaintStrippers06.pdf>]

⁵ [<http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?hSDB>]

understanding. Even if DTSC follows a rigorous and transparent process to select a Priority Product, the result of that selection is the requirement for additional assessment. DTSC should not, in its selection documents, imply that it has predetermined what the result of that assessment will be. To make such a decision without the benefit of the assessment would be arbitrary and capricious. Prior to complete comprehension of the Chemical(s) of Concern in the Priority Product, and prior to completion of an alternatives analysis, DTSC should refrain from using language such as “avoid using X product,” and, “...minimize exposure to X,” which has real and negative effects on the market and may be misinterpreted as a product ban.

- While DTSC intends the SCP regulation to be a continuous, science-based, iterative evaluation, recommendations such as “avoid using products that contain X”, during the draft initial Priority Product phase suggest a prejudged outcome from DTSC to consumers. Also in this regard, DTSC should avoid using identifiable brand trademarks and corporate logos on illustrations used in draft release statements.
- Although the next stage of the science-based evaluation is to conduct an Alternatives Assessment, DTSC uses language in press releases, workshops, media statements, and other publications that refer to “phase out,” “elimination,” “substitution” and other terms, as if removing the Candidate Chemical is the expected, or only reasonable result, when in fact the DTSC has seven different “regulatory responses” available to it at the conclusion of an Alternatives Assessment. To predetermine elimination of Candidate Chemicals will be the ultimate result of the regulatory process is not a science-based process as intended, but an arbitrary pronouncement.
- Therefore, DTSC should consider adopting a more constructive tone, encouraging cooperation and dialogue. The Department’s reliance on communications to initiate “market signals...[to] motivate manufacturers...to preemptively phase out Candidate Chemicals in products...”⁶ could be in conflict with the Department’s attempts to avoid “regrettable substitution.” DTSC should work with product manufacturers, encouraging them to participate in the regulatory process that was designed to be “...thoughtful, [and] science-based...creat[ing] a mechanism to avoid regrettable substitutions, which is the alternatives assessment [process].”

⁶ [Priority Products 3 Year Work Plan Background Memo, DTSC Green Ribbon Science Panel, June 25, 2014; https://dtsc.ca.gov/SCP/upload/Work_Plan_Memo_GRSP_June2014.pdf]



according to the former Director, Debbie Raphael.⁷ Therefore, rather than directing manufacturers to merely reformulate away from any and all Candidate Chemicals prior to the regulatory process, the Department should seek to work with industry to evaluate product risks and identify possible alternatives. DTSC's role as a governmental agency that regulates chemicals and products is to utilize the best available science (both exposures and hazards) to evaluate and regulate in order to protect human health and the environment, not to select "winners" and "losers" in the marketplace.

As noted in our February 2013 comments, Dow remains interested in working with DTSC to further optimize the implementation of the regulations for Safer Consumer Products. We look forward to working with DTSC to ensure the effective implementation of this regulation.

Regards,

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Addendum:

1. Dow Comments on SCP Regulations (January 2013)
2. Dow Comments on SCP Regulations (October 2012)

⁷ [Inside CalEPA Vol. 25, No. 15, April 11, 2014, Inside CalEPA Interview, "DTSC Director Raphael Defends Strategy for Green Chemistry, Reforms," p. 6]





1. Comments on SCP Regulations (January 2013)

Dow recognizes and appreciates the recent revisions to make the regulations more workable for industry; however, we urge DTSC to give thoughtful consideration to the areas where the Department could further clarify and simplify the requirements to make them more implementable. As noted in the attached addendum comments (October 2012), Dow's concerns remain focused on a fundamental premise: the SCP regulations lack clear, objective standards upon which predictability and compliance can be derived.

Dow applauds DTSC's attempt to address some of the concerns outlined by industry stakeholders in the January 2013 SCP regulations. Specifically, Dow supports the reference to the initial list of chemicals for consideration as the "Candidate Chemicals List" rather than "Chemicals of Concern." Focusing only those chemicals identified in the product-chemical combinations as "Chemicals of Concern" will hopefully mitigate the stigma and unwarranted market impact of product deselection.

While Dow also appreciates revisions that explicitly note that these regulations do not authorize DTSC to supersede requirements of other state or federal regulatory programs, adding to an already robust list of Candidate Chemicals will make it difficult to truly identify high-priority chemicals. When every chemical is a priority, none will be a priority.

The latest revision outlines a better mechanism for tailoring "Chemicals of Concern" to priority product combinations. Yet, the evaluation of these priority products remains subject to broad DTSC discretion, which might dramatically impact how the regulations are actually implemented. Moreover, with regard to the evidence to substantiate DTSC's discretionary decision-making, there are still few boundaries on the types of information and analysis that DTSC can require an entity to produce. And, there are little or no criteria for judging the sufficiency of that information and analysis.

Establishing the sufficiency under a "weight of evidence" approach is critical when evaluating the toxicity of chemical substances and the other scientific questions pertaining to human health and the environment. In addition to adequate information, Dow supports having clearly-defined criteria for evaluating hazard traits and exposure around environmental and health concerns, which is why we were disappointed with the "Practical Quantitation Limit" in lieu of a reasonable de minimis threshold of 0.1% (1000ppm). This is a threshold that has considerable precedent in the Globally





Harmonized System for Classification and Labeling (GHS) and the European Union's REACH program.

Precedent setting is not only recognized in areas of exposure assessments, but there is also precedent associated with laws protecting trade secrets. It is concerning to see that companies will still have to disclose chemical identities. The revision states that chemical identity may only be claimed as "trade secret" when the chemical is considered as an alternative and when a patent is pending for the chemical or its use. The protection of confidential business information (CBI) and trade secrets are considered sacrosanct among all business partners and industry representatives. DTSC continuously references its adherence to the existing legal framework for CBI and trade secrets laws and states that these regulations will not conflict with this existing framework. However, Dow believes that DTSC's goal of transparency may be undermined by the regulations because they compound the complexity of DTSC's trade secret determinations.



2. Comments on SCP Regulations (October 2012)

I. Chemicals of Concern

Dow supports the design of regulations that truly focus on limiting exposure to, and adverse impacts posed by, Priority Products that contain Chemicals of Concern (COCs) in consumer products. This targeted approach encourages the evaluation of chemicals and products of concern where there is a reasonable or foreseeable pathway for exposure. The current Safer Consumer Products (SCP) regulations appropriately recognize that chemicals are to be evaluated based on their individual use in specific products and for identifying a further prioritization process for chemicals found in the initial priority products. However, these regulations do not specify objective criteria by which chemicals might be identified, nor does it state which of the ~1200 chemicals will be listed as COCs.

A. Identification of Chemicals of Concern

The objective of identifying and characterizing COCs is to focus on chemicals used in consumer products that meet specific hazard criteria and have exposure and use patterns that may pose risks. However, by identifying a broad list of COCs compiled by a variety of governmental, intergovernmental and academic interests, it is difficult to truly identify high-priority chemicals. When every chemical is a priority, none will be a priority. The substances on this very large list of COCs will likely remain listed indefinitely, even if they are used safely in consumer products, or even if they are not used in consumer products at all.

There does not appear to be a dedicated public comment period for this initial list of chemicals based on other authoritative bodies. The net effect is that over 1200 chemicals will be on the initial list of COCs without a proper chance for the public to comment on them. The draft thus stigmatizes chemicals and products containing those chemicals from the outset before the regulatory process of alternatives analysis and regulatory response have taken place. This will likely result in unwarranted market impacts because the market will move quicker to product deselection while DTSC struggles to keep pace with the COC identifications. Since the regulations do not include a clear or science-based process by which the DTSC will select which chemicals and products it regulates, the inclusion of such a broad list of COCs does not provide predictability and certainty to companies.

B. Tailored Approach to Chemicals of Concern

Dow supports regulations that are based on established scientific principles that define safe conditions for use and impose requirements to assure that use is controlled within predefined safe conditions. Such a system must rely on risk assessment and risk management principles that are predictable, flexible and capable of responsibly addressing society's economic, environmental and safety requirements.

Dow suggests that DTSC develop a risk-based chemical management system that screens chemicals to develop a narrower, focused list of COCs that actually represent the greatest potential risk. Such an approach will allow DTSC to conduct a step-wise, methodical evaluation of chemicals of concern in priority consumer products, provide appropriate notice and information to the public, enhance health and environmental protection, minimize the potential burden to both the State and the regulated community, leverage the considerable work already done by other governments (which is required by statute), and avoid unwarranted negative impacts on the market.

Dow is concerned that an initial list of some ~1200 COCs will unduly alarm the public without simultaneously providing the public with the confidence needed to ensure timely resolution or disposition of the products that contain those chemicals. DTSC may well be identifying hundreds of chemicals that have little or no use in consumer products, or which pose no risk of harm in those uses.

II. **Priority Products**

Considering the magnitude of the proposed COC list, Dow believes it is appropriate for DTSC to only designate 2-5 priority products for the first 3-5 years of this program. This approach provides an opportunity for both industry and DTSC to better understand the regulatory challenges of the proposed framework. While Dow supports this approach, this portion of the regulations presents significant concerns for industry.

Dow appreciates that the Priority Products list is apparently intended to be risk-based, as it requires some consideration of exposure and the potential for harm. However, the current regulation identifies a vague process by which DTSC will prioritize and establish a list of Priority Products. It is unclear, however, how DTSC will objectively utilize the "Key Criteria" to assess and prioritize products based on a list of ~1200 potential chemicals of concern. An objective, step-by-step process should be constructed, based

on credible, scientifically valid criteria that clearly outline the process by which DTSC will identify priority products. The use of a highly subjective process based on a narrative standard is not acceptable from a scientific or public policy standpoint.

A. Key Prioritization Factors

The proposed prioritization process creates significant uncertainties. Although DTSC has indicated its goal is to prioritize a small number of products for review, the draft does not articulate a clear, step-by-step process for doing so. The draft indicates that DTSC may rely on information developed or received under the regulation, but is not limited to such information in reaching a prioritization decision. The lack of explicit description raises questions about the nature and type of information DTSC, in fact, might use to reach a decision.

B. Aggregate & Cumulative Risks

The success of the product prioritization process hinges on the evaluation of aggregate and cumulative risks. As it is currently written, it is unclear when, how often and through what process DTSC will conduct an evaluation of a chemical's aggregate and cumulative effects. It is also unclear whether this refers to a human health or an environmental assessment of aggregate and cumulative risks, or perhaps both. Dow is not convinced that such an analysis is necessary for all chemicals of concern, all priority products or all potential alternatives.

Assessing aggregate effects and risks from the total exposure to a specific chemical from all different sources and routes requires considerable data and information that manufacturers of individual products do not have and cannot readily obtain. Manufacturers and/or sellers of a given consumer product would need information on each individual consumer's occupational exposures, medication and diet, information that would surely raise privacy concerns. In addition, individual companies cannot possibly know all of the possible sources and uses of any given chemical outside of their own control, thus rendering cumulative risk analysis impossible.

The lack of a process not only presents a challenge of predictability for industry, but it also poses significant challenges for actual implementation. Cumulative risk assessment is far from settled science. Scientific bodies do not yet agree on an accepted cumulative risk assessment methodology. In the context of the

consumer product regulation, cumulative assessments would quickly become an onerous exercise with little practical meaning.

C. Weight of Evidence

The SCP regulations do not currently include any “weight of the evidence” approach for evaluating the toxicity of chemical substances and other scientific questions pertaining to human health and the environment. It is a general principle of hazard assessment that all available data must be considered and the totality of relevant and reliable information integrated in order to arrive at a scientifically-defensible decision regarding chemical hazard. These regulations do not currently have a process to evaluate credible hazard trait data in a manner that addresses the relevance, quality and significance of the data. Dow supports the integration of exposure-based traits that will allow for the prioritization of chemicals based on widely-perceived objective, scientifically-based studies that have been vetted in an open, deliberative and transparent scientific process.

D. Alternatives Analysis Exemptions

Having clearly-defined criteria for evaluating hazard traits and exposure around environmental and health concerns is integral to the success of chemicals management regulations. It appears that the approach to Alternatives Analysis Exemptions currently defined in the regulations will be arbitrary and inconsistent. Dow supports a reasonable de minimis threshold, or alternatives analysis threshold of 0.1% (1,000 ppm). This is a threshold that has considerable precedent in the Globally Harmonized System for Classification and Labeling (GHS) and the European Union’s REACH program. More importantly, it is a practical threshold that will avoid unnecessary assessments and reformulations based on the mere presence of trace amounts of a chemical of concern. DTSC should limit application of the regulation to intentionally added constituent chemicals.

While Dow appreciates DTSC’s attempt to establish a unique approach to threshold limits, or lack thereof, the inconsistency with other federal and international bodies will create an unnecessary level of confusion for implementation. What criteria will DTSC use to trigger the need to establish a different de minimis level? Also, what standards will be used to evaluate the “available information” to warrant a higher or lower level? Dow recommends



that DTSC carefully consider clarifying the process for establishing Alternatives Analysis Exemptions.

E. Minimum Detectable Concentration

The initial intent of the SCP regulations focused on minimizing potential exposure to COCs while spurring the innovation needed to select safer consumer products. Unfortunately, the current regulations are focused less on safe use and more on product deselection. Draft language indicates that DTSC will defer to the “minimum detectable concentration” level for the COC in the product. Dow is concerned that reliance on the limit of detection, in conjunction with precautionary language such as may “contribute to” adverse public health and environmental effects, and, deference to regulatory responses that provide the greatest level of “inherent protection,” is establishing a framework focused on chemical elimination rather than safe use.

III. Alternatives Analysis

The second stage of the alternatives assessment focuses on the comparison of alternatives. However, the criteria for determining a “demonstrable contribution” or a “demonstrable difference” are unclear. DTSC should define the process that will be used to evaluate factors relevant to the comparison of Priority Products and the alternatives. Dow would support the use of quantitative analysis tools like QSAR models to facilitate the comparison. These types of quantitative tools will help identify situations where there are other categories for which the alternatives are no better and possibly worse for potential toxicity or environmental hazards. Conducting comparative analysis under this rubric allows DTSC to conduct a more comprehensive review instead of merely relying on available qualitative information. Reliance on existing available information in this context presents a challenge because two purportedly “reliable” sources may not yield the same results or enjoy the same level of scientific standing. Dow recommends the use of quantitative tools that will enhance comparative assessment around exposure potential for consumer products.





IV. Duplication of Worker Exposure Standards

The overarching intent of the Safer Consumer Products regulations is to focus on exposure risks associated with consumer products. Thus, focusing on workers exposure in a retail setting seems to be an appropriate consideration for these regulations. Dow strongly believes that the scope of these regulations should focus on conventional consumer products in retail settings. There are OSHA exposure standards already in place for worker safety in industrial settings, and it would be unnecessary and duplicative for DTSC to appropriate its very limited resources in this manner. As just one of many examples, it seems reasonable to assume that the statute did not intend to contemplate additional regulations for an industrial worker filling railcars for shipment. Furthermore, some raw materials and intermediates may be “consumer products” under the regulations, and DTSC will have no authority to regulate the use of these materials outside of California. This creates a disincentive for California-based businesses, jobs, and operations. A manufacturer will actually be motivated to move out of state and sell back into California to avoid this duplicative regulation of the workplace. Not contemplated in this regulation is this “leakage” of jobs out of the state.

V. Confidential Business Information

The protection of confidential business information (CBI) and trade secrets are considered sacrosanct among all business partners and industry representatives. DTSC continuously references its adherence to the existing legal framework for CBI and trade secrets laws and states that these regulations will not conflict with this existing framework. However, Dow believes that DTSC’s goal of transparency may be undermined by the regulations because they compound the complexity of DTSC’s trade secret determinations. Several of the requirements for substantiation of trade secret claims are unnecessary and unauthorized by the statute (AB 1879) or other relevant trade secret statutes. The current framework outlines excessive requirements that should be revised.

